

Permission to Take Part in a Human Research Study

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| Protocol Title: LIFE: Low-birthweight Infant Feeding Exploration |
| Principal Investigator: Katherine Semrau, PhD [Malawi: Local Principal Investigator: Tisungane Mvalo, MD] [Tanzania: Local Principal Investigator: Dr. Karim Manji, MBBS, MMED, MPH, FTAAS, FRCP(Lon) FRCPCH (Lon)] [India: Local Principal Investigator: Shivaprasad Goudar, MD, MPHE] |
| Description of Study Population: Community leaders, religious leaders and traditional healers in the study area |
| Version Date: June 26, 2019 |

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you are community leader, religious leader, or traditional healer within the catchment area of this health facility.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this research to understand how community leaders, religious leaders, and traditional healers think about infant feeding. We want to study this topic because babies who are born low-birthweight are at higher risk of illnesses, death and poor growth than normal-weight babies. There is not a lot of information about how to improve feeding for these babies, so we hope to learn more by doing this study.

How long will I take part in this research?

This focus group will take up to 2 hours. During the focus group we will ask you a series of questions about your thoughts and beliefs on infant feeding in your community. More detailed information about the study procedures can be found under the “*What can I expect if I take part in this research?*” section.

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Is there any way being in this study could be bad for me?

There may be times when the questions make you feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. More detailed information about the risks of this study can be found under the “*What are the risks and possible discomforts?*” section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to others may include better care for low-birthweight babies because of this study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

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Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *[Site-specific contact information for the research team will be inserted here]*.

This research has been reviewed by the Harvard Longwood Medical Area Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Human Research Administration (OHRA) at +1-617-432-2157 (or toll-free at +1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

We have invited you to take part in a research study because you are community leader, religious leader, or traditional healer within the catchment area of this health facility. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?

Up to 32 community, religious and traditional leaders will take part in this research in this research site, and up to 128 will take part in this research across all research sites.

What can I expect if I take part in this research?

As a participant, you will be expected to participate in a 2-hour focus group discussion about your thoughts and beliefs on infant feeding in your community. Study staff will use a focus group guide to ask a series of open-ended questions about infant feeding. The questions we will ask are not of a personal or sensitive nature. The focus group will be audio recorded, transcribed, and analyzed to identify general themes and attitudes among all participants.

What are the risks and possible discomforts?

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There may be times when the questions make you feel uncomfortable. However, you do not need to answer any questions that make you feel uncomfortable. All participants will be asked to keep the discussion confidential and not share the identities of participants, but there is a small risk that your name and what you say could be shared with someone outside of the study.

Are there any benefits from being in this research study?

There are no direct benefits to you from your taking part in this research.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Will I be compensated for participating in this research?

| Study Site | Incentive |
|----------------------|--|
| Karnataka and Odisha | We will give you loss of wages, travel allowance and dearness allowance (DA) at the end of the focus group discussion to US \$4.00. |
| Lilongwe | We will give you the Malawi Kwacha equivalent to \$10 at the end of the focus group discussion. This amount is to cover the costs of your transport expenses to and from the location of the focus group discussion. |
| Dar es Salaam | We will give you travel allowances at the end of the focus group discussion up to 50,000 TZS. |

What will I have to pay for if I participate in this research?

It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Study staff will secure a safe, private, and quiet location for the focus group discussion. They will ensure that the space is comfortable for participants where they can speak freely without judgment (i.e. a private location outside of the facility instead of a dark/windowless room inside of the facility). Prior to the start of the focus groups the study staff will ask participants to keep any topics discussed during the discussion confidential and to not share or discuss any topics outside of the room.

The audio file will be uploaded to a secure data storage system as soon as possible. After the audio file is uploaded to the secure data storage system, it will be deleted from the audio recorder. The audio files will be shared in alignment with site-level IRBs.

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Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of these organizations involved in this research, such as Jawaharlal Nehru Medical College (India), Muhimbili University of Health and Allied Sciences (Tanzania), UNCH Project Malawi (Malawi), University of North Carolina (USA), Harvard University (USA), Emory University (USA), Brigham and Women's Hospital (USA), Boston Children's Hospital (USA), PATH (USA), Bill and Melinda Gates Foundation (USA).

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What else do I need to know?

This research is being funded by the Bill and Melinda Gates Foundation.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE

Your signature below indicates your permission to take part in this research

Name of participant

Signature / thumb impression of participant

Date

If the participant is unable to read or write:

Name of impartial witness

Date

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Signature of impartial witness

Date

Signature of person obtaining consent

Date

Printed name of person obtaining consent

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Protocol Title: LIFE: Low-birthweight Infant Feeding Exploration

Principal Investigator: Katherine Semrau, PhD

[Malawi: Local Principal Investigator: Tisungane Mvalo, MD]

[Tanzania: Local Principal Investigator: Dr. Karim Manji, MBBS, MMED, MPH, FTAAS, FRCP(Lon) FRCPC (Lon)]

[India: Local Principal Investigator: Shivaprasad Goudar, MD, MPHE]

Description of Study Population:

Mothers and immediate family members in the study area who have at least one child that is less than one year old and was low-birthweight.

Version Date: June 26, 2019

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you are a mother or immediate family member of a baby who was low-birthweight in the last year and you live within the catchment area of this health facility.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this research to understand how moms and families care for low-birthweight babies over time. We want to study this topic because babies who are born low-birthweight are at higher risk of illnesses, death and poor growth than normal-weight babies. There is not a lot of information about how to improve feeding for these babies, so we hope to learn more by doing this study.

How long will I take part in this research?

This focus groups will take up to 2 hours. During the focus group we will ask you a series of questions about how moms and families feed and care for their low-birthweight babies, as well as

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beliefs about low-birthweight babies in the community. More detailed information about the study procedures can be found under the “*What can I expect if I take part in this research?*” section.

Is there any way being in this study could be bad for me?

There may be times when the questions make you feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. More detailed information about the risks of this study can be found under the “*What are the risks and possible discomforts?*” section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to others may include better care for low-birthweight babies because of this study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

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Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *[Site-specific contact information for the research team will be inserted here]*.

This research has been reviewed by the Harvard Longwood Medical Area Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Human Research Administration (OHRA) at +1-617-432-2157 (or toll-free at +1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

You are invited to take part in this research because you are the mother or immediate family member of baby who was low-birthweight in the last year and you live within the catchment area of this health facility. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled. Refusal to participate or stopping your participation will not impact the care you or your family receives.

How many people will take part in this research?

Up to 64 mothers and immediate family members per site, and a total of up to 256 mothers and immediate family members across all study sites, will take part in this research.

What can I expect if I take part in this research?

As a participant, you will be expected to participate in a 2-hour focus group. Study staff will use a focus group guide to ask a series of open-ended questions about how moms and families feed and care for their low-birthweight babies, as well as beliefs about low-birthweight babies in the community. The focus group will be audio recorded, transcribed, and analyzed to identify general themes and attitudes among all participants.

What are the risks and possible discomforts?

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There may be times when the questions make you feel uncomfortable. However, you do not need to answer any questions that make you feel uncomfortable and you can choose what you want and don't want shared with the group. All participants will be asked to keep the discussion confidential and not share the identities of participants, but there is a small chance that other participants will not follow this request.

Can I still get medical care at <insert facility> if I choose not to participate in this research?

Yes, you may still get medical care at *[insert facility name(s)]* if you choose not to participate in this study. Your decision will not change the care you receive now or in the future. Taking part in this research is your choice. If you decide to take part in this study, you may leave/stop the study at any time. There will be no penalty to you and your medical care will not be affected. If you would like to stop participating in this research you should let us know. We will make sure that you stop the study safely.

It is possible that the investigator may ask you to stop the study before it is finished. If this happens we will tell you why and arrange for other care for you if needed.

Are there any benefits from being in this research study?

There are no direct benefits to you from your taking part in this research.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Will I be compensated for participating in this research?

| Study Site | Incentive |
|----------------------|---|
| Karnataka and Odisha | We will give you loss of wages, travel allowance and dearness allowance (DA) at the end of each completed study visit up to US \$4.00 |
| Lilongwe | We will give you the Malawi Kwacha equivalent to \$10 at the end of each completed study visit. This amount is to cover the costs of your transport expenses to and from the research clinic. |
| Dar es Salaam | We will give you travel allowances at the end of each completed study visit up to 30,000 TZS. |

What will I have to pay for if I participate in this research?

It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

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Study staff will secure a safe, private, and quiet location for the interviews. They will ensure that the space is comfortable for participants where they can speak freely without judgment (i.e. a private location outside of the facility instead of a dark/windowless room inside of the facility). Prior to the start of the focus groups the study staff will ask participants to keep any topics discussed during the discussion confidential and to not share or discuss any topics outside of the room.

The audio file will be uploaded to a secure data storage system as soon as possible. After the audio file is uploaded to the secure data storage system, it will be deleted from the audio recorder. The audio files will be shared in alignment with site-level IRBs.

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of these organizations involved in this research, such as Jawaharlal Nehru Medical College (India), Muhimbili University of Health and Allied Sciences (Tanzania), UNCH Project Malawi (Malawi), University of North Carolina (USA), Harvard University (USA), Emory University (USA), Brigham and Women's Hospital (USA), Boston Children's Hospital (USA), PATH (USA), Bill and Melinda Gates Foundation (USA).

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

A description of this study will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What else do I need to know?

This research is being funded by the Bill and Melinda Gates Foundation.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE

Your signature below indicates your permission to take part in this research

Name of participant

Permission to Take Part in a Human Research Study

Signature / thumb impression of participant

Date

If the participant is unable to read or write:

Name of impartial witness

Date

Signature of impartial witness

Date

Signature of person obtaining consent

Date

Printed name of person obtaining consent

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| Protocol Title: LIFE: Low-birthweight Infant Feeding Exploration |
| Principal Investigator: Katherine Semrau, PhD [Malawi: Local Principal Investigator: Tisungane Mvalo, MD] [Tanzania: Local Principal Investigator: Dr. Karim Manji, MBBS, MMED, MPH, FTAAS, FRCP(Lon) FRCPCH (Lon)] [India: Local Principal Investigator: Shivaprasad Goudar, MD, MPHE] |
| Description of Study Population: clinicians who are involved with infant and young child feeding and work at the study facilities |
| Version Date: June 26, 2019 |

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you are a health care worker who is involved with infant and young child feeding and work at the study facilities.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this research to understand how low-birthweight infants are cared for at your facility. We want to study this topic because babies who are born low-birthweight are at higher risk of illnesses, death and poor growth than normal-weight babies. There is not a lot of information about how to improve feeding for these babies, so we hope to learn more by doing this study.

How long will I take part in this research?

This focus group discussion will take up to 90 minutes. During the discussion, we will ask you a series of questions about how low-birthweight babies are cared for at your health facility.

More detailed information about the study procedures can be found under the “*What can I expect if I take part in this research?*” section.

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Is there any way being in this study could be bad for me?

There may be times when the questions make you feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. More detailed information about the risks of this study can be found under the “*What are the risks and possible discomforts?*” section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to others may include better care for low-birthweight babies because of this study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

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Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *[Site-specific contact information for the research team will be inserted here]*.

This research has been reviewed by the Harvard Longwood Medical Area Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Human Research Administration (OHRA) at +1-617-432-2157 (or toll-free at +1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

You are invited to take part in this research because you are a clinician who is involved with infant and young child feeding and work at the study health facility. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?

Up to 60 clinicians per site, and a total of up to 240 clinicians across all study sites, will take part in this research.

What can I expect if I take part in this research?

As a participant, you will be expected to participate in a 90-minute focus group about how low-birthweight babies are cared for at your health facility. Study staff will use a focus group guide to ask a series of open-ended questions about how low-birthweight babies may be cared for at a health facility. The questions we will ask are not of a personal or sensitive nature. The focus group will be audio recorded, transcribed, and analyzed to identify general themes and attitudes among all participants.

What are the risks and possible discomforts?

There may be times when the questions make you feel uncomfortable. However, you do not need to answer any questions that make you feel uncomfortable. All participants will be asked to keep the discussion confidential

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and not share the identities of participants, but there is a small risk that your name and what you say could be shared with someone outside of the study.

Are there any benefits from being in this research study?

There are no direct benefits to you from your taking part in this research.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Will I be compensated for participating in this research?

| Study Site | Incentive |
|----------------------|--|
| Karnataka and Odisha | We will give you loss of wages, travel allowance and dearness allowance (DA) at the end of the completed interview to US \$15.00. |
| Lilongwe | We will give you the Malawi Kwacha equivalent to \$10 at the end of each completed study visit. This amount is to cover the costs of your transport expenses to and from the interview site. |
| Dar es Salaam | We will give you travel allowances at the end of the interview up to 50,000 TZS. |

What will I have to pay for if I participate in this research?

It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Study staff will secure a safe, private, and quiet location for the focus group discussion. They will ensure that the space is comfortable for participants where they can speak freely without judgment (i.e. a private location outside of the facility instead of a dark/windowless room inside of the facility). Prior to the start of the focus groups the study staff will ask participants to keep any topics discussed during the discussion confidential and to not share or discuss any topics outside of the room.

The audio file will be uploaded to a secure data storage system as soon as possible. After the audio file is uploaded to the secure data storage system, it will be deleted from the audio recorder. The audio files will be shared in alignment with site-level IRBs.

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of these organizations involved in this research, such as Jawaharlal Nehru Medical College (India), Muhimbili University of Health and Allied Sciences (Tanzania), UNCH Project Malawi (Malawi), University of North Carolina

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(USA), Harvard University (USA), Emory University (USA), Brigham and Women's Hospital (USA), Boston Children's Hospital (USA), PATH (USA), Bill and Melinda Gates Foundation (USA).

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

A description of this study will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What else do I need to know?

This research is being funded by the Bill and Melinda Gates Foundation.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE

Your signature below indicates your permission to take part in this research

Name of participant

Signature / thumb impression of participant

Date

Signature of person obtaining consent

Date

Printed name of person obtaining consent

Permission to Take Part in a Human Research Study

Protocol Title: LIFE: Low-birthweight Infant Feeding Exploration

Principal Investigator: Katherine Semrau, PhD

[Malawi: Local Principal Investigator: Tisungane Mvalo, MD]

[Tanzania: Local Principal Investigator: Dr. Karim Manji, MBBS, MMED, MPH, FTAAS, FRCP(Lon) FRCPCH (Lon)]

[India: Local Principal Investigator: Shivaprasad Goudar, MD, MPHE]

Description of Study Population:

[key informants with expertise in supply chain, milk banks, or Ministry of Health officials with knowledge of infant and young child feeding interventions]

Version Date: June 26, 2019

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you have expertise in supply chain, milk banks, or a Ministry of Health officials with knowledge of infant and young child feeding interventions.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this research to understand infant and young child feeding interventions could be implemented at a national level. We want to study this topic because babies who are born low-birthweight are at higher risk of illnesses, death and poor growth than normal-weight babies. There is not a lot of information about how to improve feeding for these babies, so we hope to learn more by doing this study.

How long will I take part in this research?

This in-depth interview will take up to 1 hour. During the interview we will ask you a series of questions about how to implement infant and young child feeding programs on a national level.

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More detailed information about the study procedures can be found under the “*What can I expect if I take part in this research?*” section.

Is there any way being in this study could be bad for me?

There may be times when the questions make you feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. More detailed information about the risks of this study can be found under the “*What are the risks and possible discomforts?*” section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to others may include better care for low-birthweight babies because of this study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

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Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

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Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *[Site-specific contact information for the research team will be inserted here]*.

This research has been reviewed by the Harvard Longwood Medical Area Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Human Research Administration (OHRA) at +1-617-432-2157 (or toll-free at +1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

We have invited you to take part in a research study because you are a have expertise in supply chain, milk banks, or a Ministry of Health officials with knowledge of infant and young child feeding interventions. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?

Up to 12 key informants per site, and a total of up to 48 across all study sites, will take part in this research.

What can I expect if I take part in this research?

As a participant, you will be expected to participate in a 1-hour in-depth interview about how to implement infant and young child feeding programs on a national level. Study staff will use an interview guide to ask a series of open-ended questions about how you believe to be the best ways to implement infant and young feeding child feeding programs nationally. The questions we will ask are not of a personal or sensitive nature. The focus group will be audio recorded, transcribed, and analyzed to identify general themes and attitudes among all participants.

What are the risks and possible discomforts?

Permission to Take Part in a Human Research Study

There may be times when the questions make you feel uncomfortable. However, you do not need to answer any questions that make you feel uncomfortable. All participants will be asked to keep the interview confidential, but there is a small risk that your name and what you say could be shared with someone outside of the study.

Are there any benefits from being in this research study?

There are no direct benefits to you from your taking part in this research.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Will I be compensated for participating in this research?

| Study Site | Incentive |
|----------------------|--|
| Karnataka and Odisha | We will give you loss of wages, travel allowance and dearness allowance (DA) at the end of the completed interview to US \$15.00. |
| Lilongwe | We will give you the Malawi Kwacha equivalent to \$10 at the end of each completed study visit. This amount is to cover the costs of your transport expenses to and from the interview site. |
| Dar es Salaam | We will give you travel allowances at the end of the interview up to 50,000 TZS. |

What will I have to pay for if I participate in this research?

It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Study staff will secure a safe, private, and quiet location for the interviews. They will ensure that the space is comfortable for participants where they can speak freely without judgment (i.e. a private location outside of the facility instead of a dark/windowless room inside of the facility). Prior to the start of the interviews the study staff will ask participants to keep any topics discussed confidential and to not share or discuss any topics outside of the room.

The audio file will be uploaded to a secure data storage system as soon as possible. After the audio file is uploaded to the secure data storage system, it will be deleted from the audio recorder. The audio files will be shared in alignment with site-level IRBs.

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of these organizations involved

Permission to Take Part in a Human Research Study

in this research, such as Jawaharlal Nehru Medical College (India), Muhimbili University of Health and Allied Sciences (Tanzania), UNCH Project Malawi (Malawi), University of North Carolina (USA), Harvard University (USA), Emory University (USA), Brigham and Women's Hospital (USA), Boston Children's Hospital (USA), PATH (USA), Bill and Melinda Gates Foundation (USA).

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

A description of this study will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What else do I need to know?

This research is being funded by the Bill and Melinda Gates Foundation.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE

Your signature below indicates your permission to take part in this research

Name of participant

Signature / thumb impression of participant

Date

Signature of person obtaining consent

Date

Printed name of person obtaining consent

Permission to Take Part in a Human Research Study

Protocol Title: LIFE: Low-birthweight Infant Feeding Exploration

Principal Investigator: Katherine Semrau, PhD

[Malawi: Local Principal Investigator: Tisungane Mvalo, MD]

[Tanzania: Local Principal Investigator: Dr. Karim Manji, MBBS, MMED, MPH, FTAAS, FRCP(Lon) FRCPCH (Lon)]

[India: Local Principal Investigator: Shivaprasad Goudar, MD, MPHE]

Description of Study Population:

clinicians who are involved with infant and young child feeding and work at the study facilities

Version Date: June 26, 2019

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you are a clinician who is involved with infant and young child feeding and work at the study facilities.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this research to understand how low-birthweight infants are cared for at your facility. We want to study this topic because babies who are born low-birthweight are at higher risk of illnesses, death and poor growth than normal-weight babies. There is not a lot of information about how to improve feeding for these babies, so we hope to learn more by doing this study.

How long will I take part in this research?

This in-depth interview will take up to 1 hour. During the interview we will ask you a series of questions about how low-birthweight babies are cared for at your health facility.

More detailed information about the study procedures can be found under the “*What can I expect if I take part in this research?*” section.

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Is there any way being in this study could be bad for me?

There may be times when the questions make you feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. More detailed information about the risks of this study can be found under the “*What are the risks and possible discomforts?*” section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to others may include better care for low-birthweight babies because of this study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Permission to Take Part in a Human Research Study

Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *[Site-specific contact information for the research team will be inserted here]*.

This research has been reviewed by the Harvard Longwood Medical Area Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Human Research Administration (OHRA) at +1-617-432-2157 (or toll-free at +1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

You are invited to take part in this research because you are a clinician who is involved with infant and young child feeding and work at the study health facility. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?

Up to 60 clinicians per site, and a total of up to 240 clinicians across all study sites, will take part in this research.

What can I expect if I take part in this research?

As a participant, you will be expected to participate in a 1-hour in-depth interview about how low-birthweight babies are cared for at your health facility. Study staff will use an in-depth interview guide to ask a series of open-ended questions about how low-birthweight babies may be cared for at a health facility. The questions we will ask are not of a personal or sensitive nature. The focus group will be audio recorded, transcribed, and analyzed to identify general themes and attitudes among all participants.

What are the risks and possible discomforts?

There may be times when the questions make you feel uncomfortable. However, you do not need to answer any questions that make you feel uncomfortable. All participants will be asked to keep the discussion confidential

Permission to Take Part in a Human Research Study

and not share the identities of participants, but there is a small risk that your name and what you say could be shared with someone outside of the study.

Are there any benefits from being in this research study?

There are no direct benefits to you from your taking part in this research.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Will I be compensated for participating in this research?

| Study Site | Incentive |
|----------------------|--|
| Karnataka and Odisha | We will give you loss of wages, travel allowance and dearness allowance (DA) at the end of the completed interview to US \$15.00. |
| Lilongwe | We will give you the Malawi Kwacha equivalent to \$10 at the end of each completed study visit. This amount is to cover the costs of your transport expenses to and from the interview site. |
| Dar es Salaam | We will give you travel allowances at the end of the interview up to 50,000 TZS. |

What will I have to pay for if I participate in this research?

It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Study staff will secure a safe, private, and quiet location for the focus group discussion. They will ensure that the space is comfortable for participants where they can speak freely without judgment (i.e. a private location outside of the facility instead of a dark/windowless room inside of the facility). Prior to the start of the focus groups the study staff will ask participants to keep any topics discussed during the discussion confidential and to not share or discuss any topics outside of the room.

The audio file will be uploaded to a secure data storage system as soon as possible. After the audio file is uploaded to the secure data storage system, it will be deleted from the audio recorder. The audio files will be shared in alignment with site-level IRBs.

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of these organizations involved in this research, such as Jawaharlal Nehru Medical College (India), Muhimbili University of Health and Allied Sciences (Tanzania), UNCH Project Malawi (Malawi), University of North Carolina

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(USA), Harvard University (USA), Emory University (USA), Brigham and Women's Hospital (USA), Boston Children's Hospital (USA), PATH (USA), Bill and Melinda Gates Foundation (USA).

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

A description of this study will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What else do I need to know?

This research is being funded by the Bill and Melinda Gates Foundation.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE

Your signature below indicates your permission to take part in this research

Name of participant

Signature / thumb impression of participant

Date

Signature of person obtaining consent

Date

Printed name of person obtaining consent

Permission to Take Part in a Human Research Study

Protocol Title: LIFE: Low-birthweight Infant Feeding Exploration

Principal Investigator: Katherine Semrau, PhD

[Malawi: Local Principal Investigator: Tisungane Mvalo, MD]

[Tanzania: Local Principal Investigator: Dr. Karim Manji, MBBS, MMED, MPH, FTAAS, FRCP(Lon) FRCPCH (Lon)]

[India: Local Principal Investigator: Shivaprasad Goudar, MD, MPHE]

Description of Study Population:

Clinicians and leaders who are involved with infant and young child feeding and work at the study facilities

Version Date: March 5th 2020

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you are a clinician or leader who is involved with infant and young child feeding and work at the study facilities.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

As is common in the healthcare setting, changes in clinical practice are often introduced in health facilities. An example is the introduction of a new intervention to facilitate the feeding of low birthweight infants. This change would be made because some low birthweight babies are not growing well with the current feeding strategy in place. As you know, change is not easy and take a great deal of effort. We expect that doctors, nurses, community health workers, health leaders will be supported in making necessary changes.

Introducing a change in how low birthweight infants are fed is more likely to be successful if your department's context is taken into consideration as the feeding and implementation strategies are developed. The results will be shared with people developing the improved feeding strategies and supporting the implementation. We also recommend that the results are shared with you.

How long will I take part in this research?

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This survey will take up to 15 minutes to complete. The survey includes questions about your health facility. More detailed information about the study procedures can be found under the “*What can I expect if I take part in this research?*” section.

Is there any way being in this study could be bad for me?

There is a small risk that your role and what you say could be shared with someone outside of the study. The survey responses will not have your name attached to minimize the risk of your responses being identifiable. More detailed information about the risks of this study can be found under the “*What are the risks and possible discomforts?*” section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Permission to Take Part in a Human Research Study

Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research you will be asked to sign this form. A copy of the form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *[Site-specific contact information for the research team will be inserted here]*.

This research has been reviewed by the Harvard Longwood Medical Area Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Human Research Administration (OHRA) at +1-617-432-2157 (or toll-free at +1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

You are invited to take part in this research because you are a clinician or leader who is involved with infant and young child feeding and work at the study health facility. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?

Up to 65 individuals per site, and a total of up to 156 individuals across all study sites, will take part in this research.

What can I expect if I take part in this research?

As a participant, you will be expected to complete a survey that will take up to 15 minutes to complete.

What are the risks and possible discomforts?

There may be times when the questions make you feel uncomfortable. There is a small risk that your role and what you say could be shared with someone outside of the study. You can skip any questions you do not feel comfortable responding to or stop your participation at any time. The survey responses will not have your name attached to minimize the risk of your responses being identifiable.

Are there any benefits from being in this research study?

There are no direct benefits to you from your taking part in this research.

Permission to Take Part in a Human Research Study

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. Your participation in this study is voluntary. You may withdraw at any time or decline to answer any of the questions for any reason and it will not involve a penalty or loss of benefits or affect your employability. If you stop being in the research, already collected data may not be removed from the study database.

Will I be compensated for participating in this research?

You will not be compensated for your participation in this research.

What will I have to pay for if I participate in this research?

It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of these organizations involved in this research, such as Jawaharlal Nehru Medical College (India), Muhimbili University of Health and Allied Sciences (Tanzania), UNCH Project Malawi (Malawi), University of North Carolina (USA), Harvard University (USA), Emory University (USA), Brigham and Women's Hospital (USA), Boston Children's Hospital (USA), PATH (USA), Bill and Melinda Gates Foundation (USA).

All data, including transcripts, study notes, and analyses will be stored behind a firewall. In reports and publications, the data will be presented in aggregate, and will not identify you personally. Your identity will be kept strictly confidential.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

A description of this study will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What else do I need to know?

This research is being funded by the Bill and Melinda Gates Foundation.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

Permission to Take Part in a Human Research Study

I consent to participate in the study.

Permission to Take Part in a Human Research Study

| |
|--|
| Protocol Title: LIFE: Low-birthweight Infant Feeding Exploration |
| Principal Investigator: Katherine Semrau, PhD [Malawi: Local Principal Investigator: Tisungane Mvalo, MD] [Tanzania: Local Principal Investigator: Dr. Karim Manji, MBBS, MMED, MPH, FTAAS, FRCP(Lon) FRCPCH (Lon)] [India: Local Principal Investigator: Shivaprasad Goudar, MD, MPHE] |
| Description of Study Population: Low-birthweight newborns and their surrogates who live within the catchment area of the study health facility. |
| Version Date: June 26, 2019 |

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you have been designated as a surrogate by a mother for her and her baby with low-birthweight and you live within the catchment area of this health facility.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this research to understand how healthcare workers provide care to low-birthweight babies in this health facility and to understand how moms feed their babies over time. We want to study this topic because babies who are born low-birthweight are at higher risk of illnesses, death and poor growth than normal-weight babies. There is not a lot of information about how to improve feeding for these babies, so we hope to learn more by doing this study.

How long will I take part in this research?

We will follow up with you and the baby over a six-month period. We will start by completing a baseline visit. During the first six weeks, we will ask you to make four study visits. Over the remaining 18 weeks we will ask that you make four additional visits. The first study visit could take up to 3 hours and all other study visits could take up to 2 hours. If the baby becomes sick and is brought to the health facility during the six-month study period, we may ask you additional

Permission to Take Part in a Human Research Study

questions and take additional measurements of the baby during the baby's sick visit.

You will be asked to answer a series of questions about the baby's diet and health. We will also measure the baby by taking his/her weight, height, length, head circumference and middle upper arm circumference at each study visit. We will ask you to write down any time the baby gets sick on an illness diary.

If you feed the baby during our study visit we will observe how the baby eats. If you miss a study visit, the study team may come to your/the baby's home for the study visit, and while there, we may observe where food is prepared for the baby.

More detailed information about the study procedures can be found under the "*What can I expect if I take part in this research?*" section.

Is there any way being in this study could be bad for me?

The frequent study visits may be burdensome for you. There may be times when the questions, feeding observations or measurements make you or the baby feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. More detailed information about the risks of this study can be found under the "*What are the risks and possible discomforts?*" section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to others may include better care for low-birthweight babies because of this study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Permission to Take Part in a Human Research Study

Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *[Site-specific contact information for the research team will be inserted here]*.

This research has been reviewed by the Harvard Longwood Medical Area Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Human Research Administration (OHRA) at +1-617-432-2157 (or toll-free at +1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

You are invited to take part in a research study because you have been designated as a surrogate by a mother for her and her baby with low-birthweight and you live within the catchment area of this health facility. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?

About 850 mothers and babies per sites, and a total of about 3400 mother and babies across all study sites, will take part in this research.

What can I expect if I take part in this research?

As a participant, you will be expected to complete the following:

We will follow up with you and the baby over a six-month period. We will start by completing a baseline visit. During the next six weeks, we will ask you to make four study visits. Over the remaining 18 weeks we will ask that you make four additional visits. will be asked to return to the clinic with the baby for each follow up visit. Efforts will be made to schedule the clinic visits to coincide with your regularly scheduled standard of care visits. When this this not possible, you can choose either home visits or to come in for a clinic study visit. If you miss a facility visit, then study staff will make a home visit.

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If the baby becomes sick and is brought to the health facility during the six-month study period, we will ask you questions about the baby's illness and take additional measurements of the baby during the baby's sick visit at the health facility. We will check to see if you are comfortable before proceeding to collect study data during the baby's sick visit.

The first study visit could take up to three hours. All other study visits could take up to two hours.

During the study visits, you will be asked to answer a series of questions about the baby's diet and health. We will also measure the baby by taking his/her weight, height, length, head circumference and middle upper arm circumference at each study visit.

Starting at the week 6 follow up, we will ask you to write down any time the baby gets sick on an illness diary at home. If the baby does not have an illness you do not need to fill anything out. The diaries will be given out at the week 6 follow-up visit. The purpose of the diaries is for you to record daily details on specific illnesses experienced by your baby (diarrhea, vomiting, fever and respiratory infections) in between monthly study visits. You will be asked to tick the corresponding box when the baby has the corresponding symptoms. At subsequent monthly follow-up visits, you will bring the completed illness diaries to the study team and will be given a fresh set of blank illness diaries for the next month.

If you feed the baby during our study visit we may observe how the baby eats. If you miss a study visit, the study team may come to your/the baby's home for the study visit, and while there, we may observe where food is prepared for the baby.

In addition to speaking with you and observing the baby's feeding, we will record information from the mother's medical chart about her health, including her HIV status if known, that is relevant for the care and feeding of the baby

What are the risks and possible discomforts?

The frequent study visits may be burdensome for you and clinic attendance may be costly from both a monetary and time perspective. There may be times when the questions, feeding observations or measurements make you or the baby feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. If you do not feel comfortable being observed while feeding your baby, please tell a member of the study team. You can stop your participation at any time. If you choose to not participate, your clinical care will not be affected.

Are there any benefits from being in this research study?

There are no direct benefits to you from your taking part in this research.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Can I still get medical care at [local facility name] if I choose not to participate in this research?

Yes, you may still get medical care at [local facility name(s)] if you choose not to participate in this study. Your decision will not change the care you receive now or in the future. Taking part in this

Permission to Take Part in a Human Research Study

research is your choice. If you decide to take part in this study, you may leave/stop the study at any time. There will be no penalty to you and your medical care will not be affected. If you would like to stop participating in this research you should let us know. We will make sure that you stop the study safely.

It is possible that the investigator may ask you to stop the study before it is finished. If this happens we will tell you why and arrange for other care for you if needed.

Will I be compensated for participating in this research?

| Study Site | Incentive |
|----------------------|---|
| Karnataka and Odisha | We will give you loss of wages, travel allowance and dearness allowance (DA) at the end of each completed study visit up to US \$4.00, if you come to the study hospital for a follow up visit. |
| Lilongwe | We will give you the Malawi Kwacha equivalent to \$10 at the end of each completed study visit. This amount is to cover the costs of your transport expenses to and from the research clinic. |
| Dar es Salaam | We will give you travel allowances at the end of each completed study visit up to 10,000 TZS. |

What will I have to pay for if I participate in this research?

It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of these organizations involved in this research, such as Jawaharlal Nehru Medical College (India), Muhimbili University of Health and Allied Sciences (Tanzania), UNCH Project Malawi (Malawi), University of North Carolina (USA), Harvard University (USA), Emory University (USA), Brigham and Women's Hospital (USA), Boston Children's Hospital (USA), PATH (USA), Bill and Melinda Gates Foundation (USA).

All data, including study notes and analyses will be stored behind a firewall. In reports and publications, the data will be presented in aggregate, and will not identify you personally. Your identity will be kept strictly confidential.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Permission to Take Part in a Human Research Study

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What else do I need to know?

This research is being funded by the Bill and Melinda Gates Foundation.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE

Part I: Your signature below indicates your permission to take part in this research

Name of participant

Signature / thumb impression of participant

Date

Part III: Signature of Person Obtaining Consent

Signature of person obtaining consent

Date

Printed name of person obtaining consent

Permission to Take Part in a Human Research Study

If the participant is unable to read or write:

Name of impartial witness

Date

Signature of impartial witness

Date

Permission to Take Part in a Human Research Study

| |
|--|
| Protocol Title: LIFE: Low-birthweight Infant Feeding Exploration |
| Principal Investigator: Katherine Semrau, PhD [Malawi: Local Principal Investigator: Tisungane Mvalo, MD] [Tanzania: Local Principal Investigator: Dr. Karim Manji, MBBS, MMED, MPH, FTAAS, FRCP(Lon) FRCPCH (Lon)] [India: Local Principal Investigator: Shivaprasad Goudar, MD, MPHE] |
| Description of Study Population: Low birthweight infants and their mothers who live within the catchment area of the study health facility. |
| Version Date: June 26, 2019 |

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because your baby is low-birthweight and you live within the catchment area of this health facility.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this research to understand how healthcare workers provide care to low-birthweight babies in this health facility and to understand how moms feed their babies over time. We want to study this topic because babies who are born low-birthweight are at higher risk of illnesses, death and poor growth than normal-weight babies. There is not a lot of information about how to improve feeding for these babies, so we hope to learn more by doing this study.

How long will I take part in this research?

We will follow up with you and your baby over a six-month period. We will start by completing a baseline visit. During the first six weeks, we will ask you to make four study visits. Over the remaining 18 weeks we will ask that you make four additional visits. The first study visit could take up to 3 hours and all other study visits could take up to 2 hours. If your baby becomes sick and is

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brought to the health facility during the six-month study period, we may ask you additional questions and take additional measurements of your baby during your baby's sick visit.

You will be asked to answer a series of questions about your baby's diet as well as about you and your baby's health. We will also measure your baby by taking his/her weight, height, length, head circumference and middle upper arm circumference at each study visit and we will measure you by taking your weight and height at the first visit, at six-weeks and at the last visit. We will ask you to write down any time your baby gets sick on an illness diary.

If you feed your baby during our study visit we will observe how your baby eats. If you miss a study visit, the study team may come to your home for the study visit, and while there, we may observe where food is prepared for the baby.

More detailed information about the study procedures can be found under the "*What can I expect if I take part in this research?*" section.

Is there any way being in this study could be bad for me?

The frequent study visits may be burdensome for you. There may be times when the questions, feeding observations or measurements make you or your baby feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. More detailed information about the risks of this study can be found under the "*What are the risks and possible discomforts?*" section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to others may include better care for low-birthweight babies because of this study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Permission to Take Part in a Human Research Study

Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *[Site-specific contact information for the research team will be inserted here]*.

This research has been reviewed by the Harvard Longwood Medical Area Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Human Research Administration (OHRA) at +1-617-432-2157 (or toll-free at +1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

You are invited to take part in this research because your baby is low-birthweight and you live within the catchment area of this health facility. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?

About 850 mothers and babies per sites, and a total of about 3400 mother and babies across all study sites, will take part in this research.

What can I expect if I take part in this research?

As a participant, you will be expected to complete the following:

We will follow up with you and your baby over a six-month period. We will start by completing a baseline visit. During the next six weeks, we will ask you to make four study visits. Over the remaining 18 weeks we will ask that you make four additional visits. You will be asked to return to the clinic with your baby for each follow up visit. Efforts will be made to schedule the clinic visits to coincide with your regularly scheduled standard of care visits. When this is not possible, you can choose either home visits or to come in for a clinic study visit. If you miss a facility visit, then study staff will make a home visit.

Permission to Take Part in a Human Research Study

If your baby becomes sick and is brought to the health facility during the six-month study period, we will ask you questions about your baby's illness during your baby's sick visit at the health facility. We will check to see if you are comfortable before proceeding to collect study data during your baby's sick visit.

The first study visit could take up to three hours. All other study visits could take up to two hours.

During the study visits, you will be asked to answer a series of questions about your baby's diet as well as about you and your baby's health. We will also measure your baby by taking his/her weight, height, length, head circumference and middle upper arm circumference at each study visit. We will measure you by taking your weight and height at the first visit, and your weight again at six-weeks and at the last visit.

Starting at the week 6 follow-up visit, we will ask you to write down any time your baby gets sick on an illness diary at home. If your baby does not have an illness you do not need to fill anything out. The diaries will be given out at the week 6 follow-up visit. The purpose of the diaries is for you to record daily details on specific illnesses experienced by your baby (diarrhea, vomiting, fever and respiratory infections) in between monthly study visits. You will be asked to tick the corresponding box when your baby has the corresponding symptoms. At subsequent monthly follow-up visits, you will bring the completed diaries to the study team and will be given a fresh set of blank illness diaries for the next month.

If you feed your baby during our study visit we may observe how your baby eats. If you miss a study visit, the study team may come to your home for the study visit, and while there, we may observe where food is prepared for the baby.

In addition to speaking with you and observing the baby's feeding, we will record information from the mother's medical chart about her health, including her HIV status if known, that is relevant for the care and feeding of the baby

What are the risks and possible discomforts?

The frequent study visits may be burdensome for you and clinic attendance may be costly from both a monetary and time perspective. There may be times when the questions, feeding observations or measurements make you or your baby feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. If you do not feel comfortable being observed while feeding your baby, please tell a member of the study team. You can stop your participation at any time. If you choose to not participate, your clinical care will not be affected.

Are there any benefits from being in this research study?

There are no direct benefits to you from your taking part in this research.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Permission to Take Part in a Human Research Study

Can I still get medical care at [local facility name] if I choose not to participate in this research?

Yes, you may still get medical care at [local facility name(s)] if you choose not to participate in this study. Your decision will not change the care you receive now or in the future. Taking part in this research is your choice. If you decide to take part in this study, you may leave/stop the study at any time. There will be no penalty to you and your medical care will not be affected. If you would like to stop participating in this research you should let us know. We will make sure that you stop the study safely.

It is possible that the investigator may ask you to stop the study before it is finished. If this happens we will tell you why and arrange for other care for you if needed.

Will I be compensated for participating in this research?

| Study Site | Incentive |
|----------------------|--|
| Karnataka and Odisha | We will give you loss of wages, travel allowance and dearness allowance (DA) at the end of each completed study visit up to US \$4.00, if you come to the study hospital for a follow up visit |
| Lilongwe | We will give you the Malawi Kwacha equivalent to \$10 at the end of each completed study visit. This amount is to cover the costs of your transport expenses to and from the research clinic. |
| Dar es Salaam | We will give you travel allowances at the end of each completed study visit up to 10,000 TZS. |

What will I have to pay for if I participate in this research?

It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of these organizations involved in this research, such as Jawaharlal Nehru Medical College (India), Muhimbili University of Health and Allied Sciences (Tanzania), UNCH Project Malawi (Malawi), University of North Carolina (USA), Harvard University (USA), Emory University (USA), Brigham and Women's Hospital (USA), Boston Children's Hospital (USA), PATH (USA), Bill and Melinda Gates Foundation (USA).

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Permission to Take Part in a Human Research Study

A description of this study will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What else do I need to know?

This research is being funded by the Bill and Melinda Gates Foundation.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE

Part I: Your signature below indicates your permission for you and your baby(ies) to take part in this research

Name of participant

Signature / thumb impression of participant

Date

Part II: Signature of Person Obtaining Consent

Signature of person obtaining consent

Date

Printed name of person obtaining consent

If the participant is unable to read or write:

Permission to Take Part in a Human Research Study

Name of impartial witness

Date

Signature of impartial witness

Date

Permission to Take Part in a Human Research Study

| |
|--|
| Protocol Title: LIFE: Low-birthweight Infant Feeding Exploration |
| Principal Investigator: Katherine Semrau, PhD [Malawi: Local Principal Investigator: Tisungane Mvalo, MD] [Tanzania: Local Principal Investigator: Dr. Karim Manji, MBBS, MMED, MPH, FTAAS, FRCP(Lon) FRCPCH (Lon)] [India: Local Principal Investigator: Shivaprasad Goudar, MD, MPHE] |
| Description of Study Population: Low-birthweight newborns who were born at the study site and their surrogates. |
| Version Date: June 26, 2019 |

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you are surrogate respondent for a baby/babies born at this health facility and the baby is of low-birthweight.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this research to understand how healthcare workers provide care to low-birthweight babies in this health facility. We want to study this topic because babies who are born low-birthweight are at higher risk of illnesses, death and poor growth than normal-weight babies. There is not a lot of information about how to improve feeding for these babies, so we hope to learn more by doing this study.

How long will I take part in this research?

We will observe you and the baby periodically until the baby is discharged from this health facility. The first observation will take three hours. After that, each observation will take up to 45 minutes and will happen every 3-4 hours during the daytime. After one week, if the baby is still in the facility, we may decrease our observations to once per day. If you and the baby are separated, we

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will follow the baby in order to understand how he/she is fed while you are separated.

During each observation we will ask you a series of questions about how the baby has been feeding. If you feed the baby during our observation we will observe how the baby eats.

We may also measure the baby by taking his/her weight, length, head circumference and middle upper arm circumference.

More detailed information about the study procedures can be found under the “*What can I expect if I take part in this research?*” section.

Is there any way being in this study could be bad for me?

There may be times when the questions or feeding observations make you feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. More detailed information about the risks of this study can be found under the “*What are the risks and possible discomforts?*” section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to others may include better care for low-birthweight babies because of this study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Permission to Take Part in a Human Research Study

Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *[Site-specific contact information for the research team will be inserted here]*.

This research has been reviewed by the Harvard Longwood Medical Area Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Human Research Administration (OHRA) toll-free at +1-866-606-0573 or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

You are invited to take part in this research because you have been designated as a surrogate respondent for a baby with low-birthweight who was born at a study health facility. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?

About 95 mothers and their babies per site, and a total of up to 380 mothers and babies across all study sites, will take part in this research.

What can I expect if I take part in this research?

As a participant, you will be expected to complete the following:

We will observe you and the baby periodically until the baby is discharged from this health facility. The first observation will take three hours. After that, each observation will take up to 45 minutes and will happen every 3-4 hours during the daytime. After one week, we may decrease our observations to once per day. If you and the baby are separated, we will follow the baby in order to understand how he/she is fed while you are separated.

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During each observation we will ask you a series of questions about how the baby has been feeding. If you feed the baby during our observation we will observe how the baby eats.

We may also measure the baby by taking his/her weight, length, head circumference and middle upper arm circumference at the time of enrollment and at the time of discharge.

In addition to speaking with you and observing the baby's feeding, we will record information from the mother's medical chart about her health, including her HIV status if known, that is relevant for the care and feeding of the baby

What are the risks and possible discomforts?

If you do not feel comfortable being observed, please let a member of the study team know to stop the observation. You can also skip any questions you do not feel comfortable responding to. You can stop your participation at any time. There is also a small risk that your name and what you say could be shared with someone outside of the study. The study team will take steps to protect your data.

Are there any benefits from being in this research study?

There are no direct benefits to you from your taking part in this research.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Can I still get medical care at [local facility name] if I choose not to participate in this research?

Yes, you may still get medical care at [local facility name(s)] if you choose not to participate in this study. Your decision will not change the care you receive now or in the future. Taking part in this research is your choice. If you decide to take part in this study, you may leave/stop the study at any time. There will be no penalty to you and your medical care will not be affected. If you would like to stop participating in this research you should let us know. We will make sure that you stop the study safely.

It is possible that the investigator may ask you to stop the study before it is finished. If this happens we will tell you why and arrange for other care for you if needed.

Will I be compensated for participating in this research?

You will not be compensated for your participation in this research. However, in Tanzania surrogates will receive 10,000 Tsh.

What will I have to pay for if I participate in this research?

It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Permission to Take Part in a Human Research Study

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of these organizations involved in this research, such as Jawaharlal Nehru Medical College (India), Muhimbili University of Health and Allied Sciences (Tanzania), UNCH Project Malawi (Malawi), University of North Carolina (USA), Harvard University (USA), Emory University (USA), Brigham and Women's Hospital (USA), Boston Children's Hospital (USA), PATH (USA), Bill and Melinda Gates Foundation (USA).

All data, including study notes and analyses will be stored behind a firewall. In reports and publications, the data will be presented in aggregate, and will not identify you personally. Your identity will be kept strictly confidential.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

A description of this study will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What else do I need to know?

This research is being funded by the Bill and Melinda Gates Foundation.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE

Part I: Your signature below indicates your permission to take part in this research

Name of participant

Permission to Take Part in a Human Research Study

Signature / thumb impression of participant

Date

Part II: Signature of Person Obtaining Consent

Signature of person obtaining consent

Date

Printed name of person obtaining consent

If the participant is unable to read or write:

Name of impartial witness

Date

Signature of impartial witness

Date

Permission to Take Part in a Human Research Study

Permission to Take Part in a Human Research Study

Protocol Title: LIFE: Low-birthweight Infant Feeding Exploration

Principal Investigator: Katherine Semrau, PhD

[Malawi: Local Principal Investigator: Tisungane Mvalo, MD]

[Tanzania: Local Principal Investigator: Dr. Karim Manji, MBBS, MMED, MPH, FTAAS, FRCP(Lon) FRCPCH (Lon)]

[India: Local Principal Investigator: Shivaprasad Goudar, MD, MPHE]

Description of Study Population: Clinicians who care for low-birthweight newborns and their mothers at the study site

Version Date: May 30, 2019

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you are a clinician who cares for low-birthweight newborns and/or their mothers at the study health facility.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this research to understand how healthcare workers provide care to low-birthweight babies in this health facility. We want to study this topic because babies who are born low-birthweight are at higher risk of illnesses, death and poor growth than normal-weight babies. There is not a lot of information about how to improve feeding for these babies, so we hope to learn more by doing this study.

How long will I take part in this research?

We will observe you while you are preparing food for infant feeds and cleaning infant feeding tools. These observations will last up to 30 minutes.

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In addition, when the mother is unavailable to answer questions about her infant feeds, you may be asked about infant feeds, which will take up to 45 minutes and occur every 3-4 hours during the day. After one week of observing each infant, we may decrease our observations to once per day.

More detailed information about the study procedures can be found under the “*What can I expect if I take part in this research?*” section.

Is there any way being in this study could be bad for me?

There may be times when the questions or feeding observations make you feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. More detailed information about the risks of this study can be found under the “*What are the risks and possible discomforts?*” section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to others may include better care for low-birthweight babies because of this study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate. The choice or not to participate will not affect your position as a clinician at this facility.

Permission to Take Part in a Human Research Study

Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *[Site-specific contact information for the research team will be inserted here]*.

This research has been reviewed by the Harvard Longwood Medical Area Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Human Research Administration (OHRA) at +1-617-432-2157 (or toll-free at +1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

You are invited to take part in this research because as a clinician at this study site you provide care for infants who are of low-birthweight. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled; it will not affect your position as a clinician at this facility.

How many people will take part in this research?

Up to 150 clinicians per site, and a total of up to 600 clinicians across all study sites, will take part in this research.

What can I expect if I take part in this research?

As a participant, you will be expected to complete the following:

We will observe you while you are preparing food for infant feeds and cleaning infant feeding tools. These observations will last up to 30 minutes.

In addition, when the mother is unavailable to answer questions about her infant feeds, you may be asked about infant feeds, which will take up to 45 minutes and occur every 3-4 hours during the day. After one

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week of observing each infant, we may decrease our observations to once per day. The study team will not interrupt clinical work.

What are the risks and possible discomforts?

There may be times when the questions or observations make you feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. If you do not feel comfortable being observed, please tell a member of the study team. You can stop your participation at any time. The identifiable data collected during the observations will not be shared with your employer.

Are there any benefits from being in this research study?

There are no direct benefits to you from your taking part in this research.

What happens if I say yes, but I change my mind later?

Your participation in this study is voluntary. You may withdraw at any time or decline to answer any of the questions for any reason and it will not involve a penalty or loss of benefits or affect your employability. If you stop being in the research, already collected data may not be removed from the study database.

Will I be compensated for participating in this research?

You will not be compensated for your participation in this research

What will I have to pay for if I participate in this research?

It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of these organizations involved in this research, such as Jawaharlal Nehru Medical College (India), Muhimbili University of Health and Allied Sciences (Tanzania), UNCH Project Malawi (Malawi), University of North Carolina (USA), Harvard University (USA), Emory University (USA), Brigham and Women's Hospital (USA), Boston Children's Hospital (USA), PATH (USA), Bill and Melinda Gates Foundation (USA).

All data, including study notes and analyses will be stored behind a firewall. In reports and publications, the data will be presented in aggregate, and will not identify you personally. Your identity will be kept strictly confidential.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Permission to Take Part in a Human Research Study

A description of this study will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What else do I need to know?

This research is being funded by the Bill and Melinda Gates Foundation.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE

Your signature below indicates your permission to take part in this research

Name of participant

Signature / thumb impression of participant

Date

Signature of person obtaining consent

Date

Printed name of person obtaining consent

Permission to Take Part in a Human Research Study

Protocol Title: LIFE: Low-birthweight Infant Feeding Exploration

Principal Investigator: Katherine Semrau, PhD

[Malawi: Local Principal Investigator: Tisungane Mvalo, MD]

[Tanzania: Local Principal Investigator: Dr. Karim Manji, MBBS, MMED, MPH, FTAAS, FRCP(Lon) FRCPCH (Lon)]

[India: Local Principal Investigator: Shivaprasad Goudar, MD, MPHE]

Description of Study Population: Low-birthweight newborns and their mothers who gave birth at the study site and thus may have their feeding patterns and care observed.

Version Date: June 26, 2019

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you gave birth to your baby at this health facility and your baby is low-birthweight.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this research to understand how healthcare workers provide care to low-birthweight babies in this health facility. We want to study this topic because babies who are born low-birthweight are at higher risk of critical illnesses and poor growth than normal-weight babies. There is not a lot of information about how to improve feeding for these babies, so we hope to learn more by doing this study.

How long will I take part in this research?

We will observe you and your baby periodically until your baby is discharged from this health facility. The first observation will take three hours. After that, each observation will take up to 45

Permission to Take Part in a Human Research Study

minutes and will happen every 3-4 hours during the daytime. After one week, if your baby is still in the facility, we may decrease our observations to once per day. If you and your baby are separated, we will follow your baby in order to understand how he/she is fed while you are separated.

During each observation we will ask you a series of questions about how your baby has been feeding. If you feed your baby during our observation we will observe how your baby eats.

We may also measure your baby by taking his/her weight, length, head circumference and middle upper arm circumference.

More detailed information about the study procedures can be found under the “*What can I expect if I take part in this research?*” section.

Is there any way being in this study could be bad for me?

There may be times when the questions or feeding observations make you feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. More detailed information about the risks of this study can be found under the “*What are the risks and possible discomforts?*” section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to others may include better care for low-birthweight babies because of this study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Permission to Take Part in a Human Research Study

Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *[Site-specific contact information for the research team will be inserted here]*.

This research has been reviewed by the Harvard Longwood Medical Area Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Human Research Administration (OHRA) toll-free at +1-866-606-0573 or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

You are invited to take part in this research because your baby is low-birthweight and you live within the catchment area of this health facility. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?

About 95 mothers and babies per site, and a total of up to 380 mothers and babies across all study sites, will take part in this research.

What can I expect if I take part in this research?

As a participant, you will be expected to complete the following:

We will observe you and your baby periodically until your baby is discharged from this health facility. The first observation will take three hours. After that, each observation will take up to 45 minutes and will happen every 3-4 hours during the daytime. After one week, we may decrease our observations to once per day. If you and your baby are separated, we will follow your baby in order to understand how he/she is fed while you are separated.

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During each observation we will ask you a series of questions about how your baby has been feeding. If you feed your baby during our observation we will observe how your baby eats.

We may also measure your baby by taking his/her weight, length, head circumference and middle upper arm circumference at the time of enrollment and at the time of discharge.

In addition to speaking with you and observing your baby's feeding, we will record information from your medical chart about your health (including your HIV status if known) that is relevant for the care and feeding of your baby.

What are the risks and possible discomforts?

There may be times when the questions or feeding observations make you feel uncomfortable. If you do not feel comfortable being observed, please let a member of the study team know to stop the observation. You can also skip any questions you do not feel comfortable responding to. You can stop your participation at any time. There is also a small risk that your name and what you say could be shared with someone outside of the study. The study team will take steps to protect your data.

Are there any benefits from being in this research study?

There are no direct benefits to you from your taking part in this research.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Can I still get medical care at [local facility name] if I choose not to participate in this research?

Yes, you may still get medical care at [local facility name(s)] if you choose not to participate in this study. Your decision will not change the care you receive now or in the future. Taking part in this research is your choice. If you decide to take part in this study, you may leave/stop the study at any time. There will be no penalty to you and your medical care will not be affected. If you would like to stop participating in this research you should let us know. We will make sure that you stop the study safely.

It is possible that the investigator may ask you to stop the study before it is finished. If this happens we will tell you why and arrange for other care for you if needed.

Will I be compensated for participating in this research?

You will not be compensated for your participation in this research. However, in Tanzania mothers will receive 10,000 Tsh.

Permission to Take Part in a Human Research Study

What will I have to pay for if I participate in this research?

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I consent to participate in the study.

SIGNATURE

Part I: Your signature below indicates your permission for you and your baby(ies) to take part in this research

Permission to Take Part in a Human Research Study

Name of participant

Signature / thumb impression of participant

Date

Part II: Signature of Person Obtaining Consent

Signature of person obtaining consent

Date

Printed name of person obtaining consent

If the participant is unable to read or write:

Name of impartial witness

Date

Signature of impartial witness

Date